

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Maria S. Gawryl, Robert A. Houtchens and William R. Light  
Application No.: 10/018,529 Group Art Unit: 1651  
Filed: June 3, 2002 Examiner: Not Provided  
Confirmation No.: 4904  
Title: PRESERVING A HEMOGLOBIN BLOOD SUBSTITUTE WITH A  
TRANSPARENT OVERWRAP

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202	
on <u>1-2-03</u>	<u>Hollie Wakefield</u>
Date	Signature
<b>HOLLIE WAKEFIELD</b>	
Typed or printed name of person signing certificate	

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
P.O. Box 2327  
Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references (AA-AB4, AL-AO & AR-AW3) are enclosed.
  - ☐ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☒ The "concise explanation" requirement (non-English references) for references AN and AO under 37 CFR 1.98(a)(3) is satisfied by:
  - ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☒ the enclosed English language abstracts.

[X] Applicants requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. 09/349,290, by Maria S. Gawryl, Robert A. Houtchens and William R. Light, filed July 7, 1999, Docket No.: 1161.1027-013

\_\_\_\_ U.S. Patent Application No. 09/912,254, by Maria S. Gawryl, Robert A. Houtchens and William R. Light, filed July 24, 2001, Docket No.: 1161.1027-051

\_\_\_\_ U.S. Patent Application No. 10/018,599, by Maria S. Gawryl, Robert A. Houtchens and William R. Light, filed May 22, 2002, Docket No.: 1161.1027-064

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

[X] A copy of each above-cited application, including the current claims, is enclosed.

[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

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Dated: 12/21/02

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
1161.1027-072APPLICATION NO.  
10/018,529INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

December 31, 2002

(Use several sheets if necessary)

APPLICANT  
Maria S. Gawryl et al.FILING DATE  
June 3, 2002CONFIRMATION NO.  
4904GROUP  
1651

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AA	4,001,200	01/04/77	Bonsen et al.
	AB	4,001,401	01/04/77	Bonsen et al.
	AC	4,053,590	10/11/77	Bonsen et al.
	AD	4,061,736	12/06/77	Morris et al.
	AE	4,140,162	02/20/79	Gajewski et al.
	AF	4,460,365	07/17/84	Ganshirt et al.
	AG	4,561,110	12/24/85	Herbert
	AH	4,670,417	06/02/87	Iwasaki et al.
	AI	4,699,816	10/13/87	Galli

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	2 107 191 A	27-Apr-83	Great Britain			
	AM	WO 89/12456	28-Dec-89	PCT			
	AN	39 15252 A	15-Nov-90	Germany (w/ English Abstract)			
	AO	06,249,848	09-Sept-94	Japan (w/ English Abstract)			

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Antonini, E. et al., "Sickling and Hemoglobin S Gelation," In <i>Methods in Enzymology Volume 76 Hemoglobins</i> , eds. (NY:Academic Press), pp. 765, 769-770 (1981)
AS	Biro, G.P. et al., "Early Deleterious Hemorheologic Changes Following Acute Experimental Coronary Occlusion and Salutary Antihyperviscosity Effect of Hemodilution with Stroma-Free Hemoglobin," <i>American Heart Journal</i> , 103(5):870-878 (1992)
AT	Biro, G.P. and Beresford-Kroeger, D., "The Effect of Hemodilution with Stroma-Free Hemoglobin and Dextran on Collateral Perfusion of Ischemic Myocardium in the Dog," <i>American Heart Journal</i> , 99(1):64-75 (1980)

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PTC-1449 REPRODUCED		ATTORNEY DOCKET NO. 1161.1027-072		APPLICATION NO. 10/018,529	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION  December 31, 2002  (Use several sheets if necessary)		APPLICANT Maria S. Gawryl et al.			
		FILING DATE June 3, 2002		CONFIRMATION NO. 4904	
GROUP 1651					
U.S. PATENT DOCUMENTS					
EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE		NAME
	AJ	4,778,697	10/18/88		Genske et al.
	AK	4,826,811	05/02/89		Sehgal
	AA2	4,826,955	05/02/89		Akkapeddi et al.
	AB2	4,857,636	08/15/89		Hsia
	AC2	4,861,867	08/29/89		Estep
	AD2	5,045,529	09/03/91		Chiang
	AE2	5,051,353	09/24/91		Stratton et al.
	AF2	5,084,558	01/28/92		Rausch et al.
	AG2	5,100,401	03/31/92		Patel
	AH2	5,167,657	12/01/92		Patel
	AI2	5,178,884	01/12/93		Goodrich et al.
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	AU	Chu, D., et al., Abstract 80.13., "The Effect of Hemodilution with a Purified Monomer or Purified Bovine Hemoglobin on Infarct Size in Focal Ischemia in Rabbits," <i>Society for Neuroscience Abstracts</i> , 20:180 (1994), presented at the 24 <sup>th</sup> Annual Meeting Society of Neuroscience, Miami Beach, FL (Nov. 13-18, 1994)			
	AV	Cole, D. J. et al., "Focal Cerebral Ischemia in Rats: Effect of Hypervolemic Hemodilution with Diaspirin Cross-Linked Hemoglobin versus Albumin on Brain Injury and Edema," <i>Anesthesiology</i> , 78(2):335-342 (1993)			
	AW	Cole, D. J. et al., "Focal Cerebral Ischemia in Rats: Effect of Hemodilution with $\alpha$ - $\alpha$ Cross-Linked Hemoglobin on CBF," <i>J. Cereb. Blood Flow Metab.</i> , 12 (6):971-976 (1992)			
	AX	Cole, D. J. et al., "Effects of Viscosity and Oxygen Content on Cerebral Blood Flow in Ischemic and Normal Rat Brain," <i>Journal of Neurological Sciences</i> , 124:15-20 (1994)			
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EXAM- INER INI- TIAL		DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AJ2	5,189,146	02/23/93	Hsia
	AK2	5,194,590	03/16/93	Sehgal et al.
	AA3	5,234,903	08/10/93	Nho et al.
	AB3	5,264,555	11/23/93	Shorr et al.
	AC3	5,281,360	01/25/94	Hong et al.
	AD3	5,296,465	03/22/94	Rausch et al.
	AE3	5,296,466	03/22/94	Kilbourn et al.
	AF3	5,322,161	06/21/94	Shichman et al.
	AG3	5,334,706	08/02/94	Przybelski
	AH3	5,352,773	10/04/94	Kandler et al.
	AI3	5,356,709	10/18/94	Woo et al.
	AJ3	5,439,882	08/08/95	Feola et al.
	AK3	5,683,768	11/04/97	Shang et al.

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AY	DeVenuto, F., "Stability of Hemoglobin Solution During Extended Storage," <i>J. Lab. Clin. Med.</i> , 92(6):946-952 (December 1975)
	AZ	Dodrill, R. et al., "Barrier Coated Polyester Films for Healthcare Packaging," Conference Paper Presented at the Polyester in Healthcare Packaging, pp. 1-17 [online] (1996) [retrieved on 99-04-28] Retrieved from the Internet <URL:http://www.rollprint.com/news/barrier.htm>
	AR2	Feola, M. et al., "Clinical Trial of a Hemoglobin Based Blood Substitute in Patients with Sick Cell Anemia," <i>SURGERY, Gynecology &amp; Obstetrics</i> , 174:379-386 (1992)
	AS2	Feola, M. et al., "Improved Oxygenation of Ischemic Myocardium by Hemodilution with Stroma-Free Hemoglobin Solution," <i>CHEST</i> , 75(3):369-375 (1979)
	AT2	"Film Preserves Blood Substitute," <i>Pharmaceutical &amp; Medical Packaging News</i> , [online] (July 1998) [retrieved on 2002-10-28]. Retrieved from the Internet <URL:http://www.devicelink.com/pmpn/archive/98/07/012.html>
	AU2	Hamilton, P. et al., "Preparation of Hemoglobin Solutions for Intravenous Infusion," <i>Hemoglobin Solution</i> , pps. 455-463

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EXAM- INER INI- TIAL	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
AA4	5,929,031	07/27/99	Kerwin et al.
AB4	6,127,043	10/03/00	Lange

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DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AV2	Hauser, C. J. and Shoemaker, W.C., "Hemoglobin Solution in the Treatment of Hemorrhagic Shock," <i>Critical Care Medicine</i> , 10(4):283-287 (1982).
AW2	Homer, L.D. et al., "Oxygen Gradients Between Red Blood Cells in the Microcirculation," <i>Hypoxia Between Red Cells</i> , Academic Press, Inc. 308-323 (1981)
AX2	Krieter, H. et al., "Effects of stroma-free polymerized bovine hemoglobin solution on oxygen transport, Global and regional blood flow in a canine model of stepwise hemodilution," <i>Anesth. Analg.</i> , 78(2) S226 (1994)
AY2	Leone, B.J., and Spahn, D.R., "Anemia, Hemodilution, and Oxygen Delivery," <i>Anesth. Analg.</i> 75:651-653 (1992)
AZ2	Paradis, N.A. et al., "Selective aortic perfusion and oxygenation: An effective adjunct to external chest compression-based cardiopulmonary resuscitation," <i>J. American College of Cardiology</i> , 23(2), 497-504 (1994)
AR3	Sarelius, I.H., Cell and Oxygen Flow in Arterioles Controlling Capillary Perfusion," <i>Am. J. Physiol.</i> 265 (Heart Circ. Physiol. 34): H1682-H1687 (1993)
AS3	Standl, T. et al., "Hemodynamics and Oxygen Transport During Complete Isovolemic Hemodilution With a New Ultrapurified Polymerized Bovine Hemoglobin Solution in a Dog Model," Paper presented at the Annual Meeting of the American Society of Anesthesiologists, Washington (1993) and at the Central European Congress of Anaesthesiology, Dresden (1993)
AT3	Teicher, B.A. et al., "Oxygenation of tumors by a hemoglobin solution," <i>J. Cancer Research and Clinical Onco</i> 120:85-90 (1993)

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AU3	Tsai, A.G. and Intaglietta, M., "Local Tissue Oxygenation During Constant Red Blood Cell Flux: A Discrete Source Analysis of Velocity and Hematocrit Changes," <i>Microvascular Research</i> , 37:308-322 (1989)
AV3	Waschke, K. et al., "Local Cerebral Blood Flow and Glucose Utilization After Blood Exchange with A Hemoglobin-Based O <sub>2</sub> Carrier in Conscious Rats," <i>Amer. J. Physiol.</i> , 265, 1243-H1248 (June 1993).
AW3	Wei, E.P. et al., "Effect of Local Change in O <sub>2</sub> Saturation of Hemoglobin on Cerebral Vasodilation from Hypoxia and Hypotension," <i>Am. J. Physiol.</i> , 265 (Heart Circ. Physiol. 34):H1439-H1443 (1993)

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